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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,140	12/30/1999	LOUISE JANE BYASS	LEVER-620X(F)	5766

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PATENT DEPARTMENT  
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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 01/07/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/308,140

Applicant(s)

BYASS ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 1, 10 and 28 October, 20002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 8-10, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 11-14, 18, 19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' supplemental amendment filed 28 October 2002 (Paper No. 22) as to the foreign priority documents is acknowledged. Applicants' amendment filed 10 October 2002 (Paper No. 21) as to addition of claim 23 and response filed 1 October 2002 (Paper No. 20) as to cancellation of claims 15 and 20, amendment of claims 1-2, 4, 7, 11-12 and 18-19, and addition of claims 21 and 22 have been entered. Also, applicant's petition for extension of time of three months has been entered. Thus, claims 1-4, 7, 11-14, 18-19 and 21-23 are pending to which the following is or remains applicable. Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-4, 7, 11-14, 18-19 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

One or more claims recite "SEQ ID NO. \_" which should be "SEQ ID NO: \_".

Claim 1 is indefinite as to "dKa"; "dKa" refers to molecular weight which abbreviation is KDa. Also, claim 1 recites "SDS-PAGE"; it should be spelled out for the first instance of use else the recitation would be unclear as to whether or not it refers to a peptide sequence.

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Claim 2 is indefinite as to “one or more fragments”; how many more fragments do the polypeptides comprise and if more than one fragment, what is the order in which the fragments are joined? See also claim 3 with regard to order of joining. Or, does “(A-E)” indicate the order or the fragment to be included? Does the recitation also encompass repetitive sequence(s) composed by the same fragment, or encompass the repetitive sequence-containing fragments plus non-repetitive sequence-containing fragment(s)?

Claim 7 is indefinite for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 7 recite that “a method of obtaining polypeptide according to claim 2” whereas claim 2 does not sets forth any steps for isolation of the polypeptide. The omitted steps are (i) obtaining biological source containing the polypeptide, and (ii) separating the polypeptide from the source and identifying (or characterizing) the isolated the polypeptide. Absence of recitation of the steps in the stepwise process renders the claim indefinite.

Claim 11 is indefinite in the recitation “...capable of specifically binding to ...”since it does not equate to indication that the specific binding must actually occur. See also claim 18.

Claim 18 is indefinite in the recitation “immunologically related to...”; does the recitation refer to that both the isolate polypeptide and the polypeptide of claim 2 share the same epitope with respect to an antibody? Or, does the recitation refer to low affinity immunological binding between antibody and antigen (*i.e.*, between the two polypeptides)? or, dose the recitation regard conformationally related (note that antibody can also recognize global folded protein with respect to discrimination of epitope recognition) regardless of identity of amino acid sequence of “epitope”?

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Claim 22 recites “in situ production” but it is not clear as to what food product is defined solely by the antifreeze protein.

The comment in the responses filed 28 October 2002 (Paper No. 22), 11 October 2002 (Paper No. 21), and 1 October 2002 (Paper No. 20) have been considered but do not address the issue raised in the above statement of rejection under 35 USC 112, the second paragraph.

***Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Griffith, M. (WO9222581).

Griffith teaches an antifreeze polypeptide having molecular weight 36 KDa characterized by SDS-polyarylamide gel electrophoresis (PAGE) (see abstract, page 8 and page 23, lines 14-19), which is derived from plant (see page 8, lines 27-35). The Griffith teaching meets the limitation of claim 1 of the current application. Thus, claim 1 is anticipated by the Griffith reference.

Claim 22 is rejected under 35 U.S.C. 102(e) as being anticipated by Lance L. *et al.* (US Pat. No. 5928877).

Lance *et al.* teach a method of recombinant expression of an antifreeze polypeptide (AFP) in a transformed cell, *e.g.*, yeast (see column 5, lines 39-62 and example 3 at column 16) and teach a food product comprising AFP (see column 4, lines 23-28) wherein the efficacy of yeast-derived AFP is not significantly affected by the presence of other molecules (*e.g.*, butter fats, milk proteins, flavoring, etc.) and thus broadens the arena of potential applicability in food systems (see column 18, lines 1-10). Because the claim does not clearly set forth where the claimed antifreeze polypeptide is produced, the reference patent anticipates claim 22 of the instant application.

The response filed 1 October 2002 asserts that the Griffith's polypeptide does not anticipate claim 1 of the current application (see page 6, the fifth paragraph). The argument is unpersuasive because Griffith does teach the disclosed polypeptide isolated from a plant cell has

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antifreeze activity and possesses a biochemical characteristic, *i.e.*, 36 KDa molecular weight (see especially abstract and the "summary of the invention at page 8, lines 12 and 26).

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu

December 19, 2002



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